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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,678	01/27/2004	Mark D. Tucker	SD-7463	9818

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EXAMINER

ANTHONY. JOSEPH DAVID

ART UNIT	PAPER NUMBER
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1714

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,678

Applicant(s)

TUCKER ET AL.

Examiner

Joseph D. Anthony

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to an aqueous decontamination formulation, classified in class 252, subclass 186.38.
 - II. Claims 8-28, drawn to a decontamination kit system, classified in class 206, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are patentable distinct inventions because Invention I is drawn to a composition, whereas Invention II is drawn to a kit that has three compartments each holding different premix component that when mixed together would make the final formulation of Invention I. It is clear that these two inventions can be readily patentable over each other and that the particulars of the Invention II (e.g. the three separate compartments) are not required to make Invention I
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Robert D. Watson on 03/02/05 a provisional election was made with traverse to prosecute the invention of Group I,

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claims 1-11, 17-21, 25-31, 33-35 and 37-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-16, 22-24, 32 and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Please note that the effective filing date of applicant's claimed invention is deemed to be the actually filing date of the application namely 01/27/2004, since the "new matter" in the present CIP application is deemed to be the lack of any requirement that the decontamination formulation actually must comprise a "solublizing compounds" selected from the group consisting of cationic surfactant, cationic hydrotrope, fatty alcohols comprising 8-20 carbon atoms and admixtures thereof. Said solublizing compounds are a required component in all applications from which the present application claims priority to.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tadros et al. WO 02/02192 A1.

WO teaches formulation for neutralization of chemical and biological toxants. The formulations may comprise mixtures of: 1) one or more of cationic surfactant, 2) long-chain fatty alcohol, 3) cationic hydrotrope, 4) an oxidant, such as hydrogen peroxide, 5) an alkali metal bicarbonate peroxide activator (**Examiner note: alkali metal bicarbonate reads on applicant's claimed "sorbent additive" of all independent claims and the carbonate salt of independent claim 17**), 6) water soluble polymer, and 7) water, see abstract, page 20, lines

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17-30, examples and claims. Applicant's claims are deemed to be directly anticipated over the examples, such as example 2.

11. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Tadros et al. U.S. Patent No. 6,566,574 or Tucker et al. U.S. Patent Number 6,723,890.

Tadros et al. teach a formulation and method of making that neutralizes the adverse health effects of both chemical and biological compounds, especially chemical warfare (CW) and biological warfare (BW) agents. The formulation of the present invention non-toxic and non-corrosive and can be delivered by a variety of means and in different phases. The formulation provides solubilizing compounds that serve to effectively render the chemical and biological compounds, particularly CW and BW compounds, susceptible to attack and at least one reactive compound that serves to attack (and detoxify or kill) the compound. The at least one reactive compound can be an oxidizing compound, a nucleophilic compound or a mixture of both. The formulation can kill up to 99.99999% of bacterial spores within one hour of exposure.

In one embodiment of the patent, the formulation comprises the following compounds.

Range of Concentration	
Compound	(wt. % of overall formulation)
one or more of cationic surfactant	0.0-10
long-chain fatty alcohol	0-1

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cationic hydrotrope	0.0-10
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hydrogen peroxide	0-4
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sodium bicarbonate	(<u>a peroxide activator</u> , see column 10, lines 58-66 and claim 21)
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0-4 (Examiner note: sodium bicarbonate reads on applicant's claimed "sorber additive" of all independent claims and the carbonate salt of independent claim 17)

water soluble polymer	0-10
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water	71-91.9, see column 12, line 58 to column 13, line 15.
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EXAMPLE 2, of the patent, teaches the following composition.

Combine the Following in 100 ml Water in the Order Shown 3.84 wt. % WITCO ADOGEN 477.TM. (50%)--Cationic hydrotrope 2.0 wt. % Alcohol mix (36.4 wt. % isobutanol, 56.4 wt. % diethyleneglycolmonobutyl ether, 7.3 wt. % dodecanol)--Long chain fatty alcohol 0.2 wt. % JAGUAR 8000.TM. polymer--Water soluble polymer Hydrochloric acid (to adjust pH to approximately 6.5)--May serve to activate the polymer and cause the mixture to attain desired viscosity 3 wt. % WITCO VARIQUA.TM. 80 MC--Cationic surfactant that may solubilize the chemical agents 1.5 wt. % 1:1 Dodecanol and diethyleneglycolmonobutyl ether--Helps stabilize the foam 2.0 wt. % Hydrogen peroxide 2.0 wt. % Sodium bicarbonate (NaHCO.sub.3)--The hydrogen peroxide and sodium bicarbonate together serve as a strong nucleophile. Applicant's claims are deemed to be directly anticipated over the examples.

Tucker et al. which is a CIP of Tadros et al. U.S. Patent Number 6,566,574, teach a formulation and method of making and using that neutralizes the adverse health effects of both chemical and biological toxants, especially chemical warfare (CW) and biological warfare (BW) agents. The aqueous formulation is non-toxic and non-corrosive and can be delivered as a long-lasting foam, spray, or fog. The formulation includes solubilizing compounds that serve to effectively render the CW or BW toxant susceptible to attack, so that a nucleophilic agent can attack the compound via a hydrolysis or oxidation reaction. The formulation can kill up to 99.99999% of bacterial spores within one hour of exposure, see abstract, examples and claims. Applicant's claims are deemed to be directly anticipated over the examples.

12. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohlus et al. U.S. Patent Application Publication NO. 2002/0132751 A1.

Kohlus et al teach detergent compositions that comprise in part: an inorganic peroxy bleach, bleach activator, such as TAED, sodium acetate or potassium acetate, optional alkali metal carbonate, surfactants, builders etc., see abstract, section [0013], [0150]-[0155]. Applicant's claims are deemed to be anticipated over examples 1-2 when the composition is added in water, see section [0175].

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13. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nakagawa et al US Patent Number 3,901,819.

Nakagawa et al. teach a composition for activating an inorganic peroxide bleaching agent comprising (A) an acetic acid ester of a monosaccharide, a disaccharide, a sugar alcohol, an internal anhydride of a sugar alcohol, or erythritol, said ester having at least 2 ester groups on the adjacent carbon atoms, and (B) an acetic acid ester of a polyhydric alcohol having a melting point not higher than about 30.degree.C., the weight ratio of the components being within the range of from 1/9 to 9/1. These are O-acetyl type bleach activators.

Nakagawa et al also teaches the conventional use of low water soluble tetracetyl ethylene diamine (TAED) which is a N-acetyl type bleach activator, see abstract, column 2, lines 1-65, Tables, and claims. Applicant's claims are deemed to be anticipated over the dry composition set forth in example 3 when it is added to water. In the alternative, applicant's invention is deemed to be obvious over Nakagawa et al since it would have been obvious to add the dry composition of example 3 to water since such a step is disclosed by the reference as how all the dry compositions are to be used for bleaching.

14. Claims 3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tadros et al. WO 02/02192 A1 or Tadros et al. U.S. Patent No. 6,566,574 or Tucker et al. U.S. Patent Number 6,723,890 or Kohlus et al. U.S. Patent Application

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Publication NO. 2002/0132751 A1, all patents individually in view of Nakagawa et al US Patent Number 3,901,819.

WO, Tadros et al and Tucker et al. individually differ from applicant's claimed invention in that there is no direct disclosure to the further addition of a bleaching activator selected from the group consisting of O-acetyl, N-acetyl, and nitrile group bleaching activators.

Nakagawa et al. teach a composition for activating an inorganic peroxide bleaching agent comprising (A) an acetic acid ester of a monosaccharide, a disaccharide, a sugar alcohol, an internal anhydride of a sugar alcohol, or erythritol, said ester having at least 2 ester groups on the adjacent carbon atoms, and (B) an acetic acid ester of a polyhydric alcohol having a melting point not higher than about 30.degree.C., the weight ratio of the components being within the range of from 1/9 to 9/1. These are O-acetyl type bleach activators.

Nakagawa et al also teaches the conventional use of low water soluble tetracetyl ethylene diamine (TAED) which is a N-acetyl type bleach activator, see abstract, column 2, lines 1-29, Tables, and claims.

It would have been obvious to one having ordinary skill in the art to use the disclosure of Nakagawa et al to O-acetyl and N-acetyl bleach activators for inorganic peroxides, such as percarbonates, as motivation to actually add them as bleaching activators to the chemical and biological neutralization formulations taught by WO, Tadros et al. or Tucker et al. for the oxidation enhancement

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benefits such activators would provide for WO's, Tadros et al's or Tucker et al's oxidizing reactive component and the formulations as a whole.

15. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hardy et al. U.S. Patent Number 4,536,314.

Hardy et al teach bleach activator, bleach and detergent compositions comprising: (a) a peroxyacid bleach precursor having the general formula I "Ac—L" wherein Ac is the acyl moiety of an organic carboxylic acid comprising an optionally substituted, linear or branched C.sub.6 -C.sub.20 alkyl or alkenyl moiety or a C.sub.6 -C.sub.20 alkyl-substituted aryl moiety and L is a leaving group, the conjugate acid of which has a pKa in the range from 4 to 13, and (b) an antioxidant. The compositions combine excellent stability, substrate-safety, water-dispersibility, granulometry and detergency performance. Applicant's claims are deemed to be anticipated over Examples 22-26 when the dry compositions are added to water.

16. Claims 3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. U.S. Patent Number 4,536,314 in view of Nakagawa et al US Patent number 3,901,819.

Hardy et al differ from applicant's claimed invention in that there is no direct disclosure to the further addition of applicant's particularly claimed water-soluble bleaching activator species.

Nakagawa et al. teach a composition for activating an inorganic peroxide bleaching agent comprising (A) an acetic acid ester of a monosaccharide, a disaccharide, a sugar alcohol, an internal anhydride of a sugar alcohol, or erythritol, said ester having at least 2 ester groups on the adjacent carbon atoms, and (B) an acetic acid ester of a polyhydric alcohol having a melting point not higher than about 30.degree.C., the weight ratio of the components being within the range of from 1/9 to 9/1. These are O-acetyl type bleach activators.

Nakagawa et al also teaches the conventional use of low water soluble tetracetyl ethylene diamine (TAED) which is a N-acetyl type bleach activator, see abstract, column 2, lines 1-29, Tables, and claims.

It would have been obvious to one having ordinary skill in the art to use the disclosure of Nakagawa et al to O-acetyl and N-acetyl bleach activators for inorganic peroxides, such as percarbonates, as motivation to actually add them as bleaching activators to the bleach formulations taught by Hardy et al for the oxidation enhancement benefits such activators would provide for the Hardy et al oxidizing reactive component and the formulations as a whole.

17. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tadros et al. WO 02/02192 A1 or Tadros et al. U.S. Patent No. 6,566,574 or Tucker et al. U.S.

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Patent Number 6,723,890 or Nakagawa et al US Patent Number 3,901,819 or Kohlus et al. U.S. Patent Application Publication NO. 2002/0132751 A1 or Hardy et al. U.S.

Patent Number 4,536,314, all said patents individually in view of Huth et al. U.S. Patent Number 6,448,062.

All said patents have been described above except for Huth et al.. This rejection builds on the rejections made above. The primary patents all differ from applicant's claimed invention in that there is no direct disclosure to the further addition of polyol drying agents such as sorbitol.

Huth et al. teach a composition for simultaneous cleaning and decontaminating a device. The composition is a per-compound oxidant in an amount effective for decontaminating the device and an enzyme in an amount effective for cleaning the device. The device may be a medical device such as an endoscope or kidney dialyzer and a plurality of devices can be cleaned using the same composition. The composition may additionally contain a corrosion inhibitor in an amount effective to prevent corrosion of a metal, a chelator, a buffer, a dye and combinations thereof, see abstract, examples and claims. Huth et al directly discloses that it is well known in the art to use polyols, such as sorbitol, as drying agents in decontamination compositions, see column 20, lines 26-41.

It would have been obvious to one having ordinary skill in the art to use the disclosure of Huth et al to polyol drying agents for decontamination formulations as motivation to actually added polyols, such as sorbitol, to the

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decontamination formulations taught by the primary references for the benefits that such drying agents would effect in said decontamination formulations.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-4 and 6-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S.

Patent No. 6,566,574 **and** over claims 1-13 and 40-57 of U.S. Patent Number

6,723,890, both patents in individually view of Nakagawa et al US Patent Number

3,901,819 for claims 10-12. All said patents have been described above and applicant's pending claims are deemed to be obvious over the claims of the primary patents in view of the secondary patent for the same reasons given by the examiner in the 35 USC 103 rejection above.

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20. Claims 1-4 and 6-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17, 20-23, and 41-50 of copending Application No. 10/251,569. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/740,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the scope of the pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/623,370. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the scope of the pending claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/850,802. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is massive overlap in the scope of the pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior-Art Cited But Not Applied

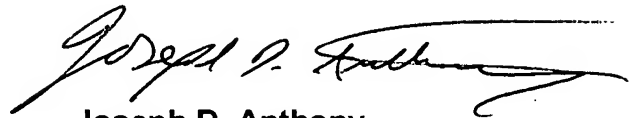
24. Any prior-art reference which is cited on FORM PTO-892 but not applied, is cited only to show the general state of the prior-art at the time of applicant's invention.

Examiner Information

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (703) 872-9306. All other papers received by FAX will be

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treated as Official communications and cannot be immediately handled by the
Examiner.

A handwritten signature in black ink, appearing to read "Joseph D. Anthony", with a long horizontal flourish extending to the right.

Joseph D. Anthony
Primary Patent Examiner
Art Unit 1714

6/17/05